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van de Gronden, J.W.; Sauter, W.

Published in:
Legal Issues of Economic Integration

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

LEGAL ISSUES OF ECONOMIC INTEGRATION

Wolters Kluwer
Law & Business

Published by:
Kluwer Law International
PO Box 316
2400 AH Alphen aan den Rijn
The Netherlands
Website: www.kluwerlaw.com

Sold and distributed in North, Central and South America by:
Aspen Publishers, Inc.
7201 McKinney Circle
Frederick, MD 21704
United States of America
Email: customer.service@aspenpublishers.com

Sold and distributed in all other countries by:
Turpin Distribution Services Ltd.
Stratton Business Park
Pegasus Drive, Biggleswade
Bedfordshire SG18 8TQ
United Kingdom
Email: kluwerlaw@turpin-distribution.com

Legal Issues of Economic Integration is published quartely (February, May, August and November).

Print subscription prices, including postage (2011): EUR 345/USD 460/GBP 253.
Online subscription prices (2011): EUR 319/USD 426/GBP 235 (covers two concurrent users).

Legal Issues of Economic Integration is indexed/abstracted in the *European Access, European Legal Journals Index, Data Juridicia*.

Printed on acid-free paper.

ISSN 1566-6573

Printed in Great Britain.

Legal Issues of Economic Integration

Law Journal of the Europa Instituut and the Amsterdam Center
for International Law, Universiteit van Amsterdam

Taking the Temperature: EU Competition Law and Health Care

Johan van de Gronden and Wolf Sauter*

While the health-care sector grows in significance due to social and technical developments, the European Union (EU) competition rules are likely to be more frequently applied to health care both as a result of the broad interpretation of the concept of undertaking and because, following the modernization of competition policy in 2003, the competition rules are also applied at the Member State level. This article charts how the case law is not always clear on the reconciliation of health-care objectives and competition rules. Hence, it pleads for soft law guidance in this area.

1. Introduction

Competition law and health care seem to come from two different worlds. Rivalry between providers and the need to cure patients may be believed to reflect conflicting values. However, during the past decades, both the European courts and the Commission have been called upon to deal with competition law and health-care cases. These cases are part of a larger development leading to the Europeanization (of some aspects) of the national health-care organization. The past twelve years have seen a rapid emergence of European Union (EU) free movement law in relation to health care. The case law of the European Court of Justice (ECJ) on services, from the emblematic *Kohll* and *Decker* cases to *Watts* and *Van Delft*, has been at the forefront of this development,[1] which has recently culminated in EU harmonization legislation with regard to patients'

* Radboud University Nijmegen; Tilburg University and Dutch Healthcare Authority, respectively. Leigh Hancher, Okeoghene Odudu, and Hans Vedder provided helpful comments on an earlier version of this text. Responsibility for any remaining errors and for the views expressed here rests with the authors.

[1] Case C-158/96, *Raymond Kohll v. Union des caisses de maladie* [1998] ECR I-1931 and Case C-120/95, *Nicolas Decker v. Caisse de maladie des employés privés* [1998] ECR I-1831; Case C-372/04, *The Queen, ex parte Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health (Watts)* [2006] ECR I-4325, and Case C-345/09, *Van Delft et al.*, judgment of 14 Oct. 2010 (nyr). Cf. J.W. van de Gronden, 'Cross-Border Healthcare in the EU and the Organization of the National Healthcare Systems of the Member States. The Dynamics Resulting from the European Court of Justice's Decisions on Free Movement and Competition Law', *Wisconsin International Law Journal* (2009): 705; A. Dawes, 'Bonjour Herr Doktor: National Healthcare Systems, the Internal Market and Cross-Border Medical Care within the EU', *Legal Issues of European Integration* (2006): 27; V.G. Hatzopoulos, 'Killing National Health and Insurance Systems but Healing Patients? The European Market for Healthcare Services after the Judgments of the ECJ in Vanbraekel and Peerbooms', *Common Market Law Review* (2002): 683.

Van de Gronden, Johan & Wolf Sauter. 'Taking the Temperature: EU Competition Law and Health Care'. *Legal Issues of Economic Integration* 38, no. 3 (2011): 213–241.

rights.[2] More recently, freedom of establishment cases have been setting new boundaries.[3] All these developments are contentious because, although the manner in which health care is organized differs widely between the Member States (while they can broadly be divided into insurance-based Bismarck systems and National Health Services (NHS) or Beveridge systems funded by taxation), in all cases public authorities are deeply involved in regulating not just the benefits but also the market structure at all levels.[4] Similar problems (such as spiralling costs) due to increased aging, rising expectations, and technical developments have also arisen, albeit from different starting points. The resultant evolution of EU free movement law is fairly well charted.

To date, the EU competition law dimension of health care is less frequently discussed in the academic literature, although the ECJ has handed down significant judgments on this subject, such as the recent ruling in the *AG2R Prévoyance* case.[5] This is noteworthy because, following the modernization of EU competition law in May 2004, the National Competition Authorities (NCAs) of the Member States have been charged with the duty to apply Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) in those instances when an EU dimension (i.e., effect upon trade between Member States) is involved.[6] Moreover, most Member States have adopted highly similar systems of national competition law in a process of spontaneous harmonization. Hence, their competition rules must be interpreted in the light of European competition law. Finally, the EU system can be relied upon in national courts as the relevant provisions of the Treaty have direct effect. As a practical result, the number of cases based on the EU competition rules before national courts will likely multiply.[7]

The application of EU competition law rules and principles to health care at the national level is, on the one hand, potentially problematic given the political sensitivities involved, while, on the other hand, it may also invigorate the sector and open new opportunities for the more efficient provision of health care. The issue is how the EU institutions will deal with competition law and health care. This leads to the question of whether specific health-care solutions will be found by these institutions and whether the application of the competition rules in this respect will be consistent.

These questions are particularly relevant to NCAs as well as national courts that are required to apply to health care either the EU competition rules or national rules

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[2] See Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border health care adopted by the European Parliament and the Council in January and February respectively OJ 2011, L88/45. See the Press Release 7056/11 of the Council of 28 Feb. 2011.

[3] See L. Hancher & W. Sauter, 'One Step beyond? From Sodemare to DocMorris: The EU's Freedom of Establishment Case Law Concerning Healthcare', *Common Market Law Review* (2010): 117. An important case in this respect is Case C-169/07, *Hartlauer Handelsgesellschaft mbH v. Wiener Landesregierung and Oberösterreichische Landesregierung* [2009] ECR I-1721.

[4] Cf. E. Mossialos, G. Permanand, R. Baeten & T.K. Hervey (eds), *Health Systems Governance in Europe: The Role of European Union Law and Policy* (Cambridge: Cambridge University Press, 2010).

[5] Case C-437/09, *AG2R Prévoyance v. Beaudout Père et Fils SARL*, judgment of 3 Mar. 2011 (nyr).

[6] Articles 3 and 5 of Council Regulation (EC) No. 1/2003 of 16 Dec. 2002 on the implementation of the rules on competition laid down in Arts 81 and 82 of the Treaty, OJ 2003, L1/1.

[7] On this matter, see H.H.B. Vedder, 'Spontaneous Harmonisation of National (Competition) Laws in the Wake of the Modernisation of EC Competition Law', *Competition Law Review* (2004): 5.

based on the former. Therefore, a further question is whether current EU competition law provides them with the adequate guidance to accomplish this.

Our approach to addressing the questions on what role health-care-specific concerns play in European competition law and whether this EU approach is sufficiently clear for national application is given as follows.

First, it should be noted that we define health care as encompassing medical care: that is, care provided by hospitals and by health-care professionals, such as general practitioners, medical specialists, and dentists. Unlike long-term care, many Member States have introduced (some) elements of competition in the organization and provision of medical care/health care.[8] This development gives rise to issues of competition law. Second, we will limit our discussion to the Treaty provisions on anticompetitive agreements between undertakings (or cartels) and the abuse of dominance as these provisions have led to cases where the specific features of health care were at stake.[9] Hence, the present contribution will explore the EU cases on Articles 101 (cartels) and 102 (dominance) TFEU. This area of EU law applies exclusively to undertakings. That is why first the EU approach to the concept of 'undertaking' in the health-care sector will be examined. Next, attention will be paid to Article 101 and subsequently to Article 102 TFEU. Before concluding, we will take a brief look at the interaction between the national and European levels of government, based on the EU law doctrines of *effet utile* and direct effect.

2. The Definition of Undertaking

Because the EU competition rules apply exclusively to (associations of) undertakings, the first issue is how to define the concept of undertaking. As a matter of national law, entities active in providing health care, managing the provision of health care, or providing health-care insurance are not regarded as undertakings. However, the EU concept is autonomous of national qualifications. How was this EU concept shaped? Did the ECJ take the view that health-care operators are not undertakings and do not fall within the scope of EU competition law, or did the ECJ decide that given

[8] See, e.g., J.W. van de Gronden & E. Szyszczak, 'Constructing a "Solid" Multi-layered Health Care Edifice', in *Health Care and EU law*, eds J.W. van de Gronden et al. (The Hague: T.M.C. Asser Press/Springer-Verlag, 2011), 481. See also the OECD Report, Enhancing Beneficial Competition in Health Professions (DAF/COMP(2005)45).

[9] To date, no significant merger case law or decisional practice, where tensions between competition and health care were at issue, is available. For example, in cases on mergers between pharmaceutical companies, the Commission mainly concentrated on the consequences of the mergers on original and generic medicines and for research and development. See, e.g., Decision of the Commission of 27 May 2005 in Case COMP/M.3751, *Novartis/Hexal*. Moreover, the Commission cleared a couple of hospital mergers as the low market shares and the limited overlap of the activities of the parties concerned did not raise any serious competition concerns. See, e.g., Decision of the Commission of 21 Aug. 2007 in Case COMP/M.4788, *Rozier/BHS*. On state aid, cf. W. Sauter & J. van de Gronden, 'State Aid, Services of General Economic Interest and Universal Service in Healthcare', *European Competition Law Review* (forthcoming, 2011). At the national level, however, interesting developments have taken place. For example, the Netherlands Competition Authority (NMa) took a remarkable decision with regard to a merger between two hospitals. It accepted an efficiency defence in order to clear this merger for reasons of preserving the quality of the hospital services concerned. See the decision of the NMa in Case 6424, *Ziekenhuis Walcheren-Oosterscheldeziekenhuizen* of 25 Mar. 2009. However, as this is a case under Dutch law, its precedential value is limited, and therefore, it will not be discussed further here. Cf. M. Canoy & W. Sauter, 'Out of Control? Hospital Mergers in the Netherlands and the Public Interest', *European Competition Law Review* (2010): 377.

the economic dimension of the services provided competition does apply? The starting point that should be stressed is that the case law of the Court on the concept of undertaking is functional in nature: this means that the formal legal definitions used in national law are irrelevant.[10] What is decisive in this context is whether the entity concerned is involved in an economic activity.[11] In this context, an economic activity is described as 'any activity consisting in offering goods and services on a given market' (in *Pavlov* and *CNOP and CCG*, see further below).[12] Would this approach cover a health-care provider or insurer, or managing body? Below, we will first examine whether health-care providers, such as hospitals, qualify as undertakings within the meaning of EU competition law. Subsequently, the concept of undertaking will be applied to national bodies managing health-care schemes (such as sickness funds and health insurance companies).

2.1. Health-care providers

As for health-care providers, the ECJ easily assumes that they are engaged in economic activities. In *Pavlov*, for example, the ECJ held that independent medical specialists perform services in a market (the market for specialized medical services), *inter alia*, because they receive remuneration for these services and assume the financial risks that are associated with their professional activity. The complexity and technical nature of their services and the fact that the practice of their profession is regulated did not affect this conclusion. Because the medical specialists were engaged in an economic activity, they were held to constitute individual undertakings in the sense of the competition rules. The same line of reasoning was deployed by the General Court in *CNOP and CCG*. In this case, it was held that pharmacists were undertakings insofar as they were independently established. As the ECJ did in *Pavlov*, the General Court stressed the point that pharmacists provide services for economic consideration at their own risk.

Providing goods and services in competition – or in a context where competition is possible (potential competition) – is likewise seen as carrying out an economic activity as an undertaking.[13] This was, for instance, held by the Court in relation to ambulance

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[10] Case 118/85, *Commission v. Italy (Transparency Directive)* [1987] ECR 2599, para. 11. On the methodology of the Court, see also W. Sauter & H. Schepel, *State and Market in European Union Law, the Public and Private Spheres of the Internal Market before the EU Courts* (Cambridge: Cambridge University Press, 2009).

[11] Case C-41/90, *Klaus Höfner and Fritz Elser v. Macrotron GmbH* [1991] ECR I-1979, para. 21.

[12] Joined Cases C-180/98 to C-184/98, *Pavel Pavlov et al. v. Stichting Pensioenfonds Medische Specialisten* [2000] ECR I-6451, para. 73 ff. (with reference to Case 118/85, *Commission v. Italy (Transparency Directive)* [1987] ECR 2599, para. 7 and Case C-35/96, *Commission v. Italy (Customs Agents)* [1998] ECR I-3851, para. 36) and Case T-23/09, *Conseil National de l'Ordre des Pharmaciens (CNOP) and Conseil Central de la Section G de l'Ordre National des Pharmaciens (CCG) v. the European Commission*, 26 Oct. 2010 (nyr), para. 70 ff. The allocation of risk is sometimes used to identify the relevant entity. Cf. Case C-22/98, *Criminal Proceedings against Jean Claude Becu et al.* [2001] ECR I-5665. The main reason for this is to delineate the application of the competition rules from the Treaty provisions on the free movement of workers. Professionals fall only within the scope of EU competition law, insofar as they are independent (self-employed) and do not fall under the authority of an employer.

[13] Case C-41/90, *Höfner*, above n. 11, paras 22 and 23.

services in the 2001 *Glöckner* case.[14] Because services such as were provided by Glöckner in the market for emergency transport and (non-emergency) patient transport are not always provided by medical aid organizations or by public authorities, these services were held to constitute an economic activity in the ECJ's view. This was not altered by the fact that some providers of such services might be less competitive as the result of public service obligations than other providers without similar obligations. Hence, the party offering these services (Glöckner) was an undertaking for the purposes of the EU competition rules. (However, due to the special characteristics of its activities, it was also found to be invested with a Service of General Economic Interest (SGEI) providing a proportional exception to the competition rules.[15]) Accordingly, in the *IRIS-Z hospitals* case, the Commission contended that services provided by the public hospitals concerned constituted economic activities as similar services were offered by private health-care operators.[16] Hence, in this decision, the argument of potential competition was also taken into account.

This actual or potential offering of services in competition test leads to the conclusion that most if not all private bodies and entities that are active in the provision of health care are likely to be found to constitute undertakings. This holds across the EU irrespective of which type of health-care provision and financing model prevails in the particular Member State concerned. Hence, it is irrelevant whether these undertaking operate in the so-called 'Bismarck systems' (in which sickness funds or other types of health insurers are the managing bodies) or in what are usually called 'Beveridge systems' (in which tax funded health-care benefits are provided by the state to its population nominally free of charge, which implies that no sickness funds or insurance companies are involved in granting benefits to patients).

In sum, the test of whether health-care providers are engaged in economic activities is not based on health-care-specific considerations. The only argument that seems to matter to the ECJ is whether competition, at least potentially, is possible. As in health care, where medical treatment is usually offered in exchange for economic consideration, competition is deemed applicable. Hence, the approach of the concept of undertaking towards health-care providers is based on a straightforward view: patients have to pay

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[14] Case C-475/99, *Firma Ambulanz Glöckner v. Landkreis Südwestpfalz* [2001] ECR I-8089.

[15] Effectively, the Court proceeds in two steps. First, it finds that there may be some elements of solidarity but that these are insufficient (in the sense that the national scheme under review is not only based on solidarity but also on competition) to exclude application of the concept of undertaking. However, subsequently, it accepts that the degree of solidarity involved is, nevertheless, sufficient to invoke Art. 106(2) TFEU on SGEI. That means the entities involved are undertakings but are shielded from the full force of competition law as they provide SGEI. This approach was pioneered in Case C-67/96, *Albany International BV v. Stichting Bedrijfspensioenfonds Textielindustrie* [1999] ECR I-5751, Joined Cases C-115/97, C-116/97, and C-117/97, *Brentjens' Handelsonderneming BV v. Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen* [1999] ECR I-6025, and Case C-219/97, *Maatschappij Drijvende Bokken BV v. Stichting Pensioenfonds voor de Vervoer- en Havenbedrijven* [1999] ECR I-6121. In more recent cases alongside the solidarity aspect, the degree of public supervision involved has been emphasized. Cf. Case C-350/07, *Kattner Stahlbau GmbH v. Maschinenbau- und Metall- Berufsgenossenschaft* [2009] ECR I-1513 and Case C-437/09, *AG2R Prévoyance*, above n. 5.

[16] See para. 109 of the Decision of the Commission of 28 Oct. 2009 with regard to state aid NN 54/2009 (ex CP 244/2005) – Belgium – financing of public hospitals of the IRIS network of the Brussels capital region.

their medical bills (either directly or indirectly), and therefore, the providers, which draw up these bills, should observe competition law.

2.2. National bodies managing health-care schemes

In contrast with the discussion above with relation to health-care providers, however, the ECJ has adopted a different approach towards national bodies managing health-care schemes, that is, providers of health insurance for publicly defined (universal) coverage, respectively, the purchasing activities of (public) health-care managing bodies. It is apparent from the more recent *AOK* and *FENIN* judgments that the activities, such as purchasing health care, of these bodies should be seen in the context of the principle of solidarity.[17] The two legs of health care, financing and provision of care, are thus treated differently.

Financial solidarity and excluding provision on market terms are the requirements for classifying a system as exclusively fulfilling a social function.[18] In this case, the entities involved are not regarded as undertakings and are excluded from the scope of competition law (but not from the market freedoms and public procurement rules that apply to public bodies).[19] This conclusion is reached taking into account the objective and compulsory nature of a system, the degree of public involvement, any elements of redistribution, and the manner in which contributions are calculated and benefits are awarded.[20]

Striking in this respect is the 2004 judgment in *AOK*.[21] At stake was the fixing of maximum contributions by the German health insurance funds towards the costs of medicinal products. The Court had been asked whether this was illegal under the competition rules. The German system made it compulsory for employees to join the public law scheme, but, on the other hand, the insurance premiums did not only depend on the income of the insured party but also on the rates set by the insurance company. There was a degree of rate competition between these insurers in order to gain the business of both those with compulsory insurance and customers who took out insurance voluntarily, with price differentials of up to 30% and up to 5% of customers switching insurers

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[17] See also J. Lear, E. Mossialos & B. Karl, 'EU Competition Law and Health Policy', in *Health Systems Governance in Europe*, above n. 4, 343.

[18] More broadly in the notion of solidarity, cf. C. Newdick, 'Citizenship, Free Movement and Healthcare: Cementing Individual Rights by Corroding Social Solidarity', *Common Market Law Review* (2006): 1645.

[19] In landmark decisions such as Case C-157/99, *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ & H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen* [2001] ECR I-5473 and Case C-385/99, *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* and *E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] I-4509, the ECJ reviewed the refusal of Dutch sickness funds to reimburse costs of cross-border health care in the light of the Treaty provisions on the free movement of services, whereas in Joined Cases C-264/01, C-306/01, C-354/01, and C-355/01, *AOK Bundesverband et al. v. Ichthyol-Gesellschaft Cordes, Hermani & Co. et al.* [2004] ECR I-2493, the ECJ held that German sickness funds were not undertakings within the meaning of EU competition law.

[20] Joined Cases C-159/91 and C-160/91, *Christian Poucet v. Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637; Case C-205/03 P, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission* [2006] ECR I-6295.

[21] Joined Cases C-264/01, C-306/01, C-354/01, and C-355/01, *AOK Bundesverband*, above n. 19. Annotated by S. Belhaj & J.W. van de Gronden, *European Competition Law Review* (2004): 682. Cf. M. Krajewski & M. Farley, 'Non-economic Activities in Upstream Markets and the Scope of Competition Law after FENIN', *European Law Review* (2007): 111.

each year. The insurance funds also implemented a risk equalization system, which made insurers with less burdensome risk profiles contribute to the financing of the funds that took care of insuring the more expensive risks. The Court held that the German health insurance funds fulfilled an exclusively social function based on the principle of solidarity and in the absence of any profit motive. In this context, the health insurance funds form a collective that is based on solidarity (or *Solidargemeinschaft*), which shares costs and risks equitably:

> The sickness funds are therefore not in competition with one another or with private institutions as regards grant of the obligatory statutory benefits in respect of treatment or medicinal products which constitutes their main function.

In addition:

> The latitude available to the sickness funds when setting the contribution rate and their freedom to engage in some competition with one another in order to attract members does not call this analysis into question.[22]

This freedom and that element of competition were only seen as a way of pursuing an efficiency gain 'in accordance with economic principles of sound management'. Therefore, the sickness funds were not considered to be undertakings and, as a result, did not fall within the scope of the competition rules.

In our view, what seems to have mattered most to the ECJ was that no competition was possible on the benefits to which patients were entitled. These benefits were fixed in national law, and as a result, the sickness funds did not enjoy any discretion when granting these benefits to insured persons. Apparently, as long as health insurers have no possibility of influencing the level of benefits, in the ECJ's view, it is not of any interest that they do compete on price.

It is clear from the outset that the outcome of the AOK test is hard to predict. For instance, a year after AOK in the state aid field, the Commission found that Dutch health insurers did constitute undertakings even though they have limited influence over the level of benefits and have comparable price differentials and switching rates to those found in AOK.[23] However, the (privatized) Dutch health insurance companies are allowed to be profit-making, and therefore, it may be assumed that this feature of the Dutch health-care organization was instrumental for the Commission in establishing the applicability of European competition law.

Another important matter to be settled was whether managing bodies for schemes that were predominately based on solidarity could qualify as undertakings when purchasing goods or services (although the managing of the schemes concerned did not constitute economic activities). The competition authorities of some EU Member States had taken the position that given their considerable impact on various health-care markets

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[22] *Ibid.*, paras 54 and 56.

[23] Decision of the Commission of 3 May 2005 with regard to state aids N 541/2004 and N 542/2004 – The Netherlands – risk equalization system and retention of reserves.

as purchasers, these bodies should observe competition law in their business relations with suppliers.[24]

However, in *FENIN* (2003, 2006), the European courts took a different route. At issue was a complaint about abuse of dominant position (based on systematic late payments to providers of medical goods and equipment by an average of 300 days) by the management bodies of the Spanish National Health System (SNS), which collectively accounted for 80% of purchases of medical goods and equipment in Spain.[25] In this case, it was accepted (or at any rate not effectively contested) that the provision of health-care services by SNS was purely of a social nature. Thereby, the main question posed to the Court became whether the purchasing activity of the management bodies should be examined as a separate activity resulting in their consideration as undertakings to which the competition rules applied. In a summarily motivated reaction, the Court held:

> (…) there is no need to dissociate the activity of purchasing goods from the subsequent use to which they are put in order to determine the nature of that purchasing activity, and [that] the nature of the purchasing activity must be determined according to whether or not the subsequent use of the purchased goods amounts to an economic activity.[26]

Consequently, there was no economic activity nor an undertaking involved, and therefore, there could be no question of applying EU competition law.

The *FENIN* logic, such as it is, clearly has important implications for NHS systems elsewhere in the EU as well, which will similarly combine public provision of care with purchasing private goods and services in the market. On the one hand, the scope of EU competition law in health care is, thus, limited. On the other hand, it may be assumed that an effective application of the rules on public procurement and state aid would discipline the exercise of public purchasing power for the greater part. This evidently makes it important that the interface between the competition rules, the state aid, and the procurement rules is well managed. As the public procurement rules oblige public bodies to contract with the most competitive service providers (or suppliers of goods), these rules are capable of restoring the imbalance between public health bodies and their contractors. Hence (as is the case for competition law), it is of great importance that public procurement law is sensitive to the specific features of health-care markets. However, because public procurement law and

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[24] For example, the Competition Commission Appeal Tribunal (CCAT)'s ruling in the *BetterCare* case found that purchasing by a public body, in certain circumstances, is an economic activity carried out by an undertaking and, therefore, may be subject to the provisions of the UK Competition Act 1998 [2002] CAT 7. The German and Dutch authorities likewise held a contrasting view. Cf., e.g., Bundesgerichtshof, Urteil vom 12 Nov. 2002, Kommunale Einkaufsgemeinschaften, Wirtschaft und Wettbewerb (2003), 625–632 and the Decision of the Director General of the NMa of 10 Mar. 2000 in Case 181, *Zorgkantoren (AWBZ Agencies)*. See also J.W. van de Gronden, 'Purchasing Care: Economic Activity or Service of General (Economic) Interest?', *European Competition Law Review* (2004): 84. For other examples of national authorities sometimes tougher approaches to competition law, see the review by Lear et al., above n. 17.

[25] See Case T-319/99, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission (FENIN)* [2003] ECR I- 357 and Case C-205/03 *P*, *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v. Commission (FENIN)* [2006] ECR I-6295.

[26] See para. 26 of the ECJ judgment in Case C-205/03, *FENIN*, above n. 25.

the state aid rules fall outside the scope of this contribution, we will not address this in further detail.[27]

An important recent case is *AG2R Prévoyance*, which concerned compulsory supplementary health insurance in France. Employers and employees in the traditional bakery sector had set up a supplementary health-care scheme and had entrusted the management of this scheme to a provident society (AG2R Prévoyance). The question arose whether AG2R Prévoyance was engaged in economic activities with regard to this task. The ECJ stressed two elements in order to establish whether competition law applied: the application of the principle of solidarity and the degree of supervision by the state.

The ECJ found that sufficient solidarity elements existed (such as the lack of a direct link between the levels of contributions and that of the benefits concerned), but that a public context in terms of supervision of the insurance scheme was lacking. The ECJ stressed that, on the one hand, the social partners, who had set up the collective insurance scheme, determined the level of benefits to which the insured persons were entitled.[28] This testified to its social nature. On the other hand, the social partners themselves selected a body for managing the health insurance scheme concerned.[29] Although they entrusted this task to AG2R, the social partners could have opted for a commercial insurance company instead. In addition, AG2R enjoyed a margin of negotiation concerning the terms of its entrustment. Hence, AG2R was held to be an undertaking engaged in an economic activity.

In sum, the ECJ carried out a two-tiered test by not only exploring the role of solidarity but also mapping the impact of the state supervisory mechanisms. This last element was introduced by the ECJ in the *Kattner Stahlbau* (2009) case,[30] with respect to the application of competition to statutory insurance against accidents at work and occupational diseases.[31] Based on *AG2R*, it now seems that the ECJ has extended this approach towards bodies managing social security schemes. Apart from being governed by the principle of solidarity, these bodies must be subject to a substantial degree of control by the state in order to escape from competition law. This implies that bodies operating in a public environment are more likely to be exempted from the competition rules than privatized bodies providing similar services. The result of this approach is that privatizing health care – and diminishing the degree of state supervision – will generally lead to the applicability of EU competition law, even in health-care systems that remain predominantly based on solidarity. After all, the absence of (substantial) state supervision will result in the ECJ ruling that the managing bodies concerned are engaged in economic activities.

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[27] See, e.g., V. Hassopoulos, 'Public Procurement and State Aid in National Health Systems', in *Health Systems Governance in Europe*, above n. 4, 379.

[28] See para. 54 of Case C-437/09, *AG2R Prévoyance*, above n. 5.

[29] *Ibid.*, paras 58–65.

[30] Case C-350/07, *Kattner Stahlbau GmbH v. Maschinen- und Metall- Berufsgenossenschaft* [2009] ECR I-1513.

[31] In Case C-218/00, *Cisal di Battistello Venanzio & C. Sas v. Istituto nazionale per l'assicurazione contro gli infortuni sul lavoro (INAIL)* [2002] ECR I-691, the ECJ already gave an initial impetus to taking into account the degree of supervision of the state with regard to the concept of undertaking.

2.3. Evaluation

The analysis carried out above shows that the European courts have developed an approach towards the concept of undertaking and bodies managing health-care schemes (as in *FENIN*), which is health-care specific. These health-care operators are only covered by the concept of undertaking insofar as they do not operate in accordance with principles that are, in the first place, predominantly based on solidarity. At the heart of this approach is solidarity. If this principle is predominant, the ECJ may decide that competition does not apply. As demonstrated, a national health-care scheme is only regarded to be predominately based on this principle if the relevant benefits are fixed in national legislation: as we have seen in *AG2R* however, this could simply mean declaring collective agreements universally binding. In other words, competition law is not applicable if the managing bodies cannot compete with regard to these benefits. However, as was shown in *AOK*, even the possibility of (a degree of) price competition is not decisive for finding that the entities concerned are engaged in economic activities. Hence, who ultimately fixes the level of benefits constitutes the crux of solidarity in health-care schemes under EU law. By incorporating solidarity in its test of undertaking, the ECJ pays due consideration to health-care-specific concerns, as solidarity is one of the constituting elements of health-care policy.

Solidarity alone, however, is not enough to escape the competition rules. The second element is that the management of such a health-care scheme should be carried out under substantial supervision by the state. Since *AG2R Prévoyance*, it could be argued that even if they are solidarity-based, only state-controlled health-care schemes may be immune from competition law. In case of a mix of solidarity and competition elements or in the absence of supervision by the state health insurers, they qualify as undertakings within the meaning of EU competition law.[32] Bodies managing a scheme that is based on a mix of solidarity and competition are obliged to observe the EU rules on competition (however, see the exception for SGEI discussed below).

Because in its case law on the concept of undertaking the ECJ attaches great value to the extent managing bodies can influence the level of benefits, it may be assumed that NHS bodies, operating in a Beveridge system with general taxation-based financing and solidarity, are more immune from competition law than are health insurers active in Bismarck systems based precisely on an insurance system. After all, in the former supply-driven tax-based system (where sickness funds or insurance companies do not play any role), governments can determine the level of benefits with precision, whereas in the latter case those governments that rely on a health insurance scheme may decide to leave some room for competition with regard to the benefits that the insured persons are entitled to (e.g., relating to supplementary insurance). Put differently, fixing the level

[32] See, e.g., Case C-244/94, *Fédération Française des Sociétés d'Assurance et al., v. Ministère de l'Agriculture et de la Pêche (FFSA)* [1995] ECR I-4015; Case C-67/96, *Albany*; Joined Cases C-115/97, C-116/97, and C-117/97, *Brentjens*; Case C-219/97, *Drijvende Bokken*, above n. 15.

of benefits by the government seems to be inherent in tax-based health-care systems, but Member States tend to be more flexible if they operate a health insurance system, leaving the parties involved more exposed to the competition rules. On top of that, supervision by the state seems a constitutive characteristic of NHS systems, whereas the state is more likely to step back in health insurance systems.[33]

It, therefore, appears that the ECJ uses an expansive concept of undertaking for health-care providers and a moderated concept for health insurers/managing bodies. The broad meaning of 'undertaking' opens the door to a multitude of health-care cases both under EU and (EU law-based) national competition laws. We now move on from the definition of undertaking to the application of the competition rules to health care in those cases where undertakings are involved, starting with anticompetitive agreements: cartels.

3. Cartel Prohibition in Health Care

The cartel prohibition applies to agreements between concerted practices of undertakings, as well as decisions of associations of undertakings. So far, there are few if any EU level decisions or judgments concerning the cartel prohibition applied to health care with the exception of the pharmaceutical sector.[34] Thus, there is little specific guidance for health-care operators carrying out a self-assessment as required under Articles 101(1) and 101(3) TFEU.

3.1. Health care and article 101 TFEU

The most significant cases that do address the application of the cartel prohibition in health care are the *GlaxoSmithKline* and *Pavlov* cases.[35]

The *GlaxoSmithKline* case is noteworthy because here the health-care-specific question of the role of insurers in respect of the costs was raised. In the pharmaceutical sector, the commercial interests of the industry, which are based on costly research protected

[33] For example, to meet the requirements of the Council Directive 92/49/EEC of 18 Jun. 1992 on the coordination of laws, regulations, and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC (Third Non-life Insurance Directive), *OJ 1992, L228/1*.

[34] Cf. L. Hancher, 'The EU Pharmaceuticals Markets: Parameters and Pathways', in *Health Systems Governance in Europe*, above n. 4. In 2008–2009, the pharmaceutical sector has been the subject of an industry-wide pan-EU sector enquiry by DG Competition, which concluded with a Commission Communication of 8 Jul. 2009, Pharmaceutical Sector Enquiry Report. This stated, *inter alia*, that it takes too long for generic medicines to reach the market and fewer innovative medicines are reaching the market, while there is an urgent need for an EU patent and patent litigation system. The Commission is to scrutinize the sector more closely and promote regulatory reform including at the national level with regard to approval procedures, clinical trials, and the uptake of generic medicines. At both levels, measures are to be taken to improve price competition.

[35] We are passing over Joined Cases C-2/01 P and C-3/01 P, *Bundesverband der Arzneimittel-Importeure eV and Commission v. Bayer AG* [2004] ECR I-23; Case T-41/96, *Bayer AG v. Commission* [2000] ECR II-3383. This revolved around the distinction between unilateral conduct, caught by Art. 102 TFEU, and concerted practices/agreements, caught by Art. 101(1) TFEU, which are mutually exclusive. Case C-446/05, *Criminal Proceedings against Doulamis* [2008] ECR I-1377, where the Court found that Art. 101 TFEU read in conjunction with Art. 4(3) of the TEU (*effet utile*) did not apply to a Belgian ban on advertising for dentists, is dealt with below under the relationship between EU and national rules.

by intellectual property (IP) rights, and the contestation of the resulting advantages clash with attempts by the Member States to contain costs. At issue in the GlaxoSmith Kline saga was its practice of maintaining differentiated prices in the Spanish market in order to block parallel imports (tariff arbitrage).[36] The Commission did establish a breach of Article 101 TFEU on this basis. The General Court, however, had focused on the question of whether restrictions of parallel imports deny benefits to consumers (or whether these benefits are substantial). In solving this question, it assigned considerable importance to the fact that the bodies managing the health-care scheme of the Member State concerned usually bear the costs of the supply of medicines. It found that, given the existence of price regulation at the national level, the benefits appeared to accrue primarily to the parallel importers themselves. It further pointed out that higher prices resulting from restrictions to the parallel trade in pharmaceuticals were not detrimental to consumers, as the managing bodies were under an obligation to reimburse them. As a result, the General Court was of the opinion that agreements containing the restrictions to parallel trade did not have the object of restricting competition. Hereby, the General Court departed from long-standing case law, according to which restrictions to parallel trade were considered to be a severe infringement of the cartel prohibition ('hard-core restriction'), which was absolutely banned in order to stimulate market integration and dated back to traditional landmark decisions such as *Grundig/Consten* in 1966.[37]

The General Court based this decision on the view that consumer welfare is the overriding goal in European competition law. Moreover, its reasoning relied on a health-care-specific argument, as it contended that the costs of the consumption of medicines are borne by the health insurers and not by the consumers, the position of which was not directly affected by the restrictive practices under review.[38] Finally, the General Court did find concrete adverse effects on competition (resulting from the agreements under review). However, this did not call into question its change of approach towards restrictions to parallel trade.

The Court of Justice approached the practices of GlaxoSmithKline differently. It stressed that apart from consumer welfare other goals (such as the market structure and competition itself) must be weighed and emphasized that the view that regards territorial restrictions as a restriction by object remains good law. However, at the end of the day, the outcome of the judgments of the ECJ and General Court did not differ substantially. After all, both Courts agreed that an infringement of Article 101 TFEU was involved, while the Commission would have to collect more information in order to be able to decide whether the exception of Article 101(3) TFEU applied.[39] The net effect

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[36] See Case T-168/01, *GlaxoSmithKline* [2006] ECR II-2969 and Joined Cases C-501/06 P, C-513/06 P, C-515/06 P, and C-519/06 P, *GlaxoSmithKline Services Unlimited v. Commission* (C-501/06 P), *Commission v. GlaxoSmithKline Services Unlimited* (C-513/06 P), *European Association of Euro Pharmaceutical Companies (EAEPC) v. Commission* (C-515/06 P), and *Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v. Commission* (C-519/06 P) [2009] I-9291.

[37] Case 56/64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v. Commission* [1966] ECR 429.

[38] See para. 131 of the General Court judgment in *GlaxoSmithKline*, above n. 36.

[39] Cf. J.W. van de Gronden, 'The Treaty Provisions on Competition and Healthcare', in *EU Law and Healthcare*, eds J.W. van de Gronden et al. (The Hague: Asser Press, 2011).

on behaviour blocking parallel trade in pharmaceuticals is that this remains prima facie illegal under EU law and a health-care-specific context is not capable of altering this point of departure.

It is a pity that in this case the ECJ did not express its views on how the traditional approach towards restrictions of parallel trade could be tailored to health care. Perhaps it neglected to do so precisely because it thought that this was a regular market where intervention to sustain prices – if necessary to remedy market failures – should be limited to public authorities. At least in its assessment under Article 101(3) TFEU, the ECJ could have elaborated on the role played by the fact that health insurers usually bear the costs.

Another noteworthy case is *Pavlov* (already mentioned in relation to the definition of 'undertaking'), which concerned a collective supplementary pension scheme set up by the Dutch organization of medical specialists. Again, a question concerning health-care-specific costs was at issue, as a comparative analysis was made between the 'financial burden' caused by this pension scheme and the expenses of the other components of the services provided by medical specialists. Here, the ECJ stressed that due account must be taken of the economic context in which the concerned undertakings operate, of the products or services covered by the decisions of those undertakings, of the structure of the market concerned, and of the actual conditions in which this market functions.[40] As the arrangement on the supplementary pension scheme standardizes only a minor part of the costs of the complex services offered by medical specialists that require expensive medical equipment and infrastructure, it did not cause an appreciable effect on competition in medical services and was, as a result, not in violation of Article 101 TFEU.[41] Here, traces of a health-care-specific approach are discernible at least in the sense that the health-care-specific facts are the foundation of the ruling: the costs of complicated medical services that require the existence of medical infrastructure and equipment totally outweigh the relative costs of a pension scheme. However, one swallow does not make a summer: to date, the ECJ has not repeated this approach when evaluating restrictions in the health-care context.

3.2. The pursuit of legitimate objectives

So far, we have seen few traces of a sector-specific approach. This does not mean that the ECJ never allows sector-specific concerns to override the competition rules: outside health care, the ECJ has opted more decisively for an approach that pays due consideration

[40] See para. 91 of Joined Cases C-180/98 to C-184/98, *Pavlov*, above n. 12.

[41] 'The decision in question produces restrictive effects only in relation to one cost factor of the services offered by self-employed medical specialists, namely the supplementary pension scheme, which is insignificant in comparison with other factors, such as medical fees or the cost of medical equipment. The cost of the supplementary pension scheme has only a marginal and indirect influence on the final cost of the services offered by self-employed medical specialists.' *Ibid*., para. 95.

to the special features of the sector involved. In the 2002 *Wouters* case,[42] for example, it was called upon to review a decision taken by the Dutch Bar Association (a ban on multidisciplinary partnerships between accountants and lawyers). The ECJ said that for the purpose of the application of Article 101 TFEU:

> (…) account must first of all be taken of the overall context in which the decision of the association of undertakings was taken or produces its effects. More particularly, account must be taken of its objectives, which are here connected with the need to make rules relating to organisation, qualifications, professional ethics, supervision and liability, in order to ensure that the ultimate consumers of legal services and the sound administration of justice are provided with the necessary guarantees in relation to integrity and experience (see, to that effect, Case C-3/95 Reisebüro Broede [1996] ECR I-6511, paragraph 38). It has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives.[43]

Eventually, the ECJ held that that the decision taken by the Dutch Bar Association was necessary given the professional ethics at stake and, therefore, not contrary to the cartel prohibition.

In *Meca-Medina* (2006),[44] the ECJ even applied the approach developed in *Wouters* to sports. At issue were anti-doping rules and the plaintiffs had argued that these rules were contrary to Article 101(1) TFEU. The ECJ put forward that the anti-doping rules issued by sports associations do not:

> (…) necessarily constitute a restriction of competition incompatible with the common market, within the meaning of Article 81 EC [now Article 101 TFEU], since they are justified by a legitimate objective. Such a limitation is inherent in the organisation and proper conduct of competitive sport and its very purpose is to ensure healthy rivalry between athletes.[45]

Remarkably, the ECJ referred in general wording to the need to achieve legitimate objectives (not public objectives), which meant that competition law was not infringed.[46] Hence, in areas other than health care, the ECJ seems to have developed an approach that is capable of accommodating issues of general interest in the application of European competition law. In *Wouters*, the ECJ focused on the issue of professional ethics and held that this issue could justify not applying Article 101 TFEU (provided that certain conditions were met). However, in *Meca-Medina*, the ECJ disconnected this approach from the specific context of professional ethics and ruled that restrictive agreements that are necessary to achieve legitimate objectives are permissible. It goes without saying that in health care such objectives may well be at stake.[47] For instance, many health-care providers are guided by a specific medical deontology (starting from the Hippocratic oath) and might apply rules that are 'inherent' in the organization of health care (one example

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[42] Case C-309/99, *J.C.J. Wouters, J.W. Savelbergh & Price Waterhouse Belastingadviseurs BV v. Algemene Raad van de Nederlandse Orde van Advocaten (Wouters)* [2002] ECR I-1577.

[43] *Ibid.*, para. 97.

[44] Case C-519/04P, *David Meca-Medina and Igor Majcen v. Commission (Meca-Medina)* [2006] ECR I-6991.

[45] *Ibid.*, para. 45.

[46] *Ibid.*

[47] See also Lear et al., above n. 17.

might be rules prohibiting doctors from advertising[48] or from using their qualifications in a non-medical setting). This deontology could plead in favour of exempting the medical profession from the application of Article 101 TFEU based on the doctrine of legitimate objectives even if certain deontological provisions could restrain competition between the members of the profession.

4. Abuse of Dominance and Health Care

Abuse of dominance concerns cases where a single undertaking has (or in exceptional cases several undertakings acting collusively have)[49] gained such a strong position on the relevant market that it is able to act independently from competitors, customers, suppliers, and/or ultimately consumers.[50] Below, we will examine how the general rules developed by the ECJ and the Commission with regard to Article 102 TFEU fit in a health-care context. Subsequently, the main case law concerning this Treaty provision and health care will be explored.

4.1. The General rules of article 102 TFEU and health care

As is well known, in order to determine whether a dominant position exists, the relevant market needs to be defined in two dimensions: the product market (e.g., hospital care) and the geographic market (e.g., a particular city or local area).[51] A classical tool for defining the market is the 'Small but Significant Non-transitory Increase in Price' (SSNIP) test, which is also frequently used by the Commission.[52] This means that by way of a thought experiment (i.e., hypothetically), the price of the product concerned is increased by 5%–10% and the reaction of customers is observed. If customers switch to other products and/or providers in significant numbers, these products and/or their providers must be added to the market because they discipline the behaviour of the provider who is being investigated. This process is repeated until there is no longer any significant substitution: thus, the market is determined.

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[48] Cf. Case T-144/99, *Institute of Professional Representatives before the European Patent Office v. Commission of the European Communities* [2001] II-1087, where the General Court held that a ban on comparative publicity issued by an association of professionals was justifiable in the light of Art. 101(3) TFEU.

[49] A tight oligopoly of several large undertakings can lead to a position of collective dominance: (1) the members must be able to observe each other's behaviour closely; (2) there has to be an enforcement mechanism against deviant behaviour (e.g., punitive price reductions); and (3) it must be impossible for outsiders such as competitors or entrants to undermine the oligopoly. Case T-342/99, *Airtours plc v. Commission* [2002] ECR II-2585.

[50] Case 85/76, *Hoffmann-La Roche & Co. AG v. Commission* [1979] ECR 461. Cf. A. Ezrachi (ed.), *Art. 82 EC: Reflections on Its Recent Evolution* (Oxford: Hart Publishers, 2009).

[51] Commission Notice on the definition of the relevant market for the purposes of Community competition law, OJ 1997, C372/5. It is also required that a significant part of the internal market be involved. This would be the case for the entire territory of a Member State or part of a larger Member State. Important infrastructural bottlenecks such as a major sea- or airport can also constitute a significant part of the internal market. Cf. Case C-179/90, *Merci convenzionali porto di Genova SpA v. Siderurgica Gabrielli SpA* [1991] ECR I-05889.

[52] See the Commission Notice, above n. 51, para. 15 ff.

From the perspective of health-care markets, the application of the SSNIP test in the context of Article 102 TFEU has significant drawbacks. (In the Article 101 TFEU setting, markets may well be formally defined, but in cartel cases, market definition is not as important as in Article 102 TFEU cases because, for Article 101 TFEU, the threshold is appreciability, not dominance.) The problems that are specific to health care arise especially in insurance-based Bismarck systems as consumers do not directly bear the costs of their treatment on account of the 'third party pays' principle. In this case, as the General Court pointed out in *GlaxoSmithKline*,[53] the insurer pays the costs of the health care consumed and because there is no direct relationship between the premiums paid by the consumer and his or her choices, the latter are hardly affected by cost.

This problem is now being addressed at the national level by health economists who have developed econometric models that are based, for instance, on the willingness of customers to travel to alternative providers (with additional travel time to next preferred options as the equivalent of a price increase) or their willingness to pay in order to include a particular provider in the package of care available to them (which takes account of the role played by insurers).[54] Market definition is not just crucial to determining the existence of dominance for abuse cases but also to merger cases (likewise largely based on dominance) and, to a lesser extent, cartel cases: especially when hard-core restrictions or restrictions by object are involved, the exact definition of the market is less important.

However, these experiments are so far taking place purely at the national level and the Commission has no significant experience with defining health-care-specific markets. This could give rise to challenges that the national models do not fit the European competition law framework and are not in line with general EU principles on market definition. At the same time, national authorities cannot be blamed for trying out state-of-the-art methods, in particular where, for example, in hospital markets, traditional methods have proven untenable.[55] Even if (as is likely the case) the new market definition methods are compatible with EU law, it would be a pity if needless legal wrangles on this point arise just because the Commission continues to rely on a very general Notice on a market definition dating from 1997. At the same time, outcomes that could turn out to be incompatible with EU law are not hypothetical. For instance, the Dutch NCA had to reconsider its approach[56] towards the concept of undertaking

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[53] Case T-168/01, *GlaxoSmithKline*, above n. 36.

[54] Cf. M. Varkevisser, 'Patient Choice, Competition and Antitrust Enforcement in Dutch Hospital Markets', PhD Thesis (Rotterdam, 2010); M. Varkevisser, C.S. Capps & F.T. Schut, 'Defining Hospital Markets for Antitrust Enforcement: New Approaches and Their Applicability to The Netherlands', *Health Economics, Policy and Law* (2008): 7–29. Initially, the Elzinga Hogarty test was applied based on the number of consumers that would travel from within a region to outside the region and vice versa. This method has been discredited in US merger practice, not least because in a 2006 case Professor Ken Hogarty testified that his method was not useful in health cases.

[55] *Ibid.*, and DOJ/FTC, *Improving Healthcare: A Dose of Competition* (US Department of Justice and Federal Trade Commission, 2004). Between 1995 and 2004, the DOJ and FTC lost a score of hospital merger cases based on unsatisfactory geographic market definitions and ended up giving up on hospital care mergers for a number of years as a result.

[56] In its view, Dutch sickness funds were undertakings, as they were engaged in price competition (with regard to the premiums) and enjoyed a wide margin of discretion when purchasing health care. In subsequent case law (*AOK* and *FENIN*), the ECJ has made clear that these arguments are not decisive for establishing the applicability of competition

in relation to sickness funds when the Court's ruling in *AOK*[57] diametrically opposed its own decisional practice.

It is well known that dominance is determined on the basis of market shares (the dividing line is 50%)[58] and other factors such as the relative market share (as compared to the next largest competitors), countervailing market power, and commercial (brands), technical (patents), and financial advantages ('deep pockets' or preferential access to capital). The existence of entry barriers as a result of law and regulation can also be relevant – especially in highly regulated sectors such as health care. This may depend on which segment of the sector is concerned, for example, entry in the hospital market is likely to be much more difficult than it would be for an individual medical practitioner (such as a general practitioner, a dentist, or a physical therapist) requiring far lower investments and a much lighter regulatory burden. Finally, the behaviour of the undertaking concerned is relevant as well: if it is in a position to impose unilaterally profitable price increases that may constitute important proof of the existence of a dominant position.

When it comes to abusive behaviour, two main types of such behaviour are generally distinguished: exploitation and exclusion. Exploitation may concern charging excessive prices (many times higher than costs and/or comparable prices[59]) with respect to consumers or other customers and has as its purpose to increase the profits of the undertaking enjoying a dominant position above competitive levels. Exclusion may concern predatory pricing (below costs[60]) or a price squeeze (not leaving a margin between consumer prices and the prices for key inputs[61]) and aims to foreclose competition by pushing competitors out of the market, thereby creating the opportunity to subsequently exploit consumers (then deprived from alternatives). In recent years, antitrust enforcers have generally given combating exclusionary abuses priority over correcting exploitative abuses. Accordingly, the European Commission (EC) has published extensive Guidance on its approach to exclusion in a communication at the end of 2008.[62] The reason behind this approach is that if exclusion is controlled effectively it will soon become superfluous to address exploitation because the latter problem will be solved by the market mechanism itself. In this context, ensuring that effective market entry is not foreclosed is important as well.

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law. See the Decision of the Dutch NCA in Case 1165, *ANOZ-ANOVA/ZAO* of 29 Dec. 1998 and the Decision in Case 882/44, *Amicon* and Case 407/49, *Texincare & Tevic v. Amicon* of 18 Jun. 1999.

[57] See the Decision of the Dutch NCA in Case 347, *Complaints of Healthcare Providers with Regard to Abusive Behaviour of Health Insurers* of 26 May 2005.

[58] Case C-62/86, *AKZO Chemie BV v. Commission* [1991] ECR I-3359, para. 60. With reference to Case 85/76, *Hoffmann-La Roche*, above n. 50, para. 41: '(…) the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position'.

[59] Such cases are highly exceptional at the EU level. One such exception is provided by Joined Cases 110/88, 241/88 and 242/88, *François Lucazeau et al. v. Société des Auteurs, Compositeurs et Editeurs de Musique (SACEM) et al.* [1989] ECR 2811.

[60] Case C-202/07 P, *France Télécom SA v. Commission* [2009] ECR I-2369.

[61] Case T-271/03, *Deutsche Telekom AG v. Commission* [2008] ECR II-477.

[62] See Press Release IP/08/1877 of 3 Dec. 2008, 'consumer welfare at heart of Commission fight against abuses by dominant undertakings'. In the first half of 2009, this new Commission policy was published in the OJ. See Communication from the Commission, Guidance on the Commission's enforcement priorities in applying Art. 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ 2009, C45/7.

Interestingly, in its Guidance, the Commission has indicated that reasons external to a dominant undertaking may be capable of justifying abusive behaviour: the Commission has expressed its intention to apply an objective necessity test to cases of dominance. The Guidance even explicitly states that '(e)xclusionary conduct may, for example, be considered objectively necessary for health or safety reasons related to the nature of the product in question'.[63] At first sight, the term 'health or safety reasons' seems to relate to product safety. However, because the Commission does not explicitly limit the interpretation of 'health or safety' to that context it cannot be excluded that health-care interests other than those connected with product safety are capable of justifying abusive behaviour.[64] In any event, the Commission appears prepared to accept that the need to realize an objective of general interest may justify practices that, at first sight, seem to be of an abusive nature. Hence, the Commission's Guidance on exclusionary behaviour may have opened the door to invoking the objective of health care in order to justify a breach of Article 102 TFEU.

4.2. Article 102 TFEU cases on health care

The analysis above makes clear that applying the general rules on dominance as developed in European competition law to health care may turn out to be problematic. How did the case law solve these difficulties? In particular, how does it make use of the exception regarding SGEI in Article 106(2) TFEU, which balances the application of the competition rules with the requirements of public interest tasks?

To date, the Commission has not acted against abuse of dominance with regard to health-care providers or insurers. However, in recent years, it has taken action on several occasions in the pharmaceuticals sector, notably IMS Health[65] and AstraZeneca.[66] IMS Health, however, did not raise major health-care-specific issues but instead focused on the (complex) relationship between IP rights and competition law. AstraZeneca manipulated the renewal procedures of its authorizations to the detriment of competing producers of generic substitutes as well as the shape in which its products were marketed to the detriment of parallel importers. However, the Commission decision did not lead to any guidance on the complex interplay between health care and competition law. Apart

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[63] *Ibid.*, para. 29 (Guidance).

[64] Although admittedly the Commission refers to cases where product-related conditions were involved: Case T-30/89, *Hilti AG v. Commission* [1991] ECR II-1439, paras 118–119; Case T-83/91, *Tetra Pak International SA v. Commission (Tetra Pak II)* [1994] ECR II-755.

[65] Case C-418/01, *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG* [2004] ECR I-5039. The Court decided that the owner of an the essential input is obligated to supply it if the undertaking that has requested a license intends to use this to create a new product, if there is no objective justification for the refusal, and if the refusal eliminates all competition from the market. An interim measure was imposed in 2003/741/EC: Commission Decision of 13 Aug. 2003 relating to a proceeding under Art. 82 of the EC Treaty (Case COMP D3/38.044, *NDC Health/IMS Health: Interim Measures*), OJ 2003, L268/69.

[66] See 2006/857/EC: Decision of the Commission of 15 Jun. 2005 relating to a proceeding under Art. 82 of the EC Treaty and Art. 54 of the EEA Agreement (Case COMP/A.37.507/F3, *AstraZeneca*), OJ 2006, L332/24. This was in line with the norm established by the Court of Justice in Joined Cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v. Commission* [1995] ECR I-743, which was relaxed by the General Court in Case T-201/04, *Microsoft Corp. v. Commission* [2007] ECR II-3601.

from this, the Court has delivered a judgment in a preliminary procedure concerning the application of Article 102 TFEU with regard to pharmaceuticals, which we will discuss in more detail as it raised some issues of principle.

In *Sot. Lélos v. GlaxoSmithKline AEVE*, the question was raised as to what extent a pharmaceutical company was allowed to defend itself against parallel imports (arbitrage between 'high price' and 'low price' Member States) by means of a refusal to supply.[67] One of the issues raised in this case was that the dominant company concerned pursued a health-care objective, that is, guaranteeing the access to medicines for all. The ECJ took the position that regulation of pharmaceuticals does not remove the abusive character from every refusal by a pharmaceutical undertaking to fulfil the orders from wholesale traders that are involved in parallel exports. However, it should be able to take reasonable and proportionate measures to defend its own commercial interests.[68] In this context, the usual size of these orders given the size of the market involved and earlier commercial relations between the parties should be taken into account. Hence, a measured response to parallel imports appears possible. Of great interest, however, is the decision the ECJ took in the *Sot. Lelos* case, with regard to the claim by the dominant firms that the contested measures were required in order to protect the planning and distribution of medicines in Greece.

The ECJ rejected this claim. After having taking into consideration the problems of shortage of medicines, it explicitly stated that:

> (…) it would not be for the undertakings holding a dominant position but for the national authorities to resolve the situation, by taking appropriate and proportionate steps that were consistent with (…) the applicable national and EU laws.[69]

Hence, it may be concluded that the ECJ rejects the idea that the pursuit of health-care objectives may justify refusal to supply. This approach does not square with the Commission's Guidance on Article 102 TFEU mentioned in the previous section. As the ECJ did not explain its position further, it is hard to understand why it did not opt for merely concluding that the claim of the undertaking concerned was not sufficiently supported by proof. The result appears to suggest tensions between EU case law in a preliminary ruling – hence, advising in national proceedings – and the Commission's Guidance on a significant issue, that is, to what extent practices of dominant undertakings may be justifiable due to the need to pursue legitimate health-care aims.

The analysis in *Sot. Lélos v. GlaxoSmithKline AEVE* illustrates that there is currently no clear view on how to apply Article 102 TFEU to health-care cases. Whereas the Commission seems to leave the door open to health-care-specific considerations in this context, the ECJ appears to reject the idea that health-care cases require special treatment. Consequently, EU competition policy on dominance abuse in health care is in a state of flux, and as a result, insufficient guidance is available.

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[67] Joined Cases C-468/06 to C-478/06, *Sot. Lélos kai Sia EE et al. v. GlaxoSmithKline AEVE* [2008] ECR I-7139.
[68] *Ibid.*, paras 69–70.
[69] See para. 75 of *Sot. Lélos kai Sia EE*, above n. 67.

Nevertheless, there are two cases involving dominance issues where the ECJ has been willing to take into account health-care-specific objectives. Both have already been mentioned in the context of defining an 'undertaking', and both concern the application of the SGEI exception.

In *Ambulanz Glöckner*, Article 102 TFEU was applied in conjunction with Article 106 TFEU to ambulance services. The policy of the authorities to allow public ambulance companies to leverage their market power from the reserved market (the emergency transport of patients) to the market that was nominally open to competition (the non-emergency transport of patients) was found to be anticompetitive. However, the ECJ held that these companies were entrusted with the task of providing SGEI within the meaning of Article 106(2) TFEU. As a result, it was accepted that the performance of this task needed to be financed by the revenues gained on the non-reserved market, in order to prevent the operation of the SGEI mission on the reserved market, the universal coverage of the emergency transport of ill people, from being put under pressure. The health-care-specific objectives of the SGEI mission, thus, played an overriding role.

Similarly, in *AG2R Prévoyance*, the ECJ held that the provident society charged with the task of managing the supplementary health-care scheme by the social partners who had set up this scheme was entrusted with carrying out an SGEI in the sense of Article 106(2) TFEU. The compulsory affiliation to this managing body was justified due to this SGEI as it would ensure that universal cover was provided and that the undertaking entrusted with the task of providing supplementary insurance for all persons insured would not end up with an increasing share of bad risks: hence, the compulsory affiliation guaranteed that the managing body concerned was able to carry out its SGEI task under economically acceptable circumstances. As in *Glöckner*, the concept of SGEI led the ECJ to accommodate health-care-specific concerns in its reasoning.

However, it is noteworthy that in *AG2R Prévoyance* the ECJ did not assign any value to the act of entrustment of the imputed SGEI. It merely derived the relevant task from the fact that the supplementary health-care scheme at issue was characterized by a high degree of solidarity.[70] Furthermore, the ECJ pointed to the constraints imposed on *AG2R* and related to the continuity of the cover granted to the persons insured. This approach is a striking departure from earlier cases where the EU Courts have gone to some trouble in order to identify the legal context from which the existence of SGEI could be derived.[71] In *AG2R*, it seems that in the view of the ECJ the mere existence of obligations (related to a general interest) imposed upon a managing body suffices to assume that this body is engaged in providing SGEI. Moreover, in this particular case, the entities, which decided on the designation of the management of the scheme concerned, were social partners, that is, the employers and trade unions representing employees in

[70] Fixed-rate contributions not proportionate to the risks insured, contributions fixed at a uniform sum, partly paid by the employer and partly by the employee, without any role for factors such as age or health.

[71] For example, Case T-289/03, *British United Provident Association Ltd (BUPA) et al. v. Commission* [2008] ECR II-81.

the traditional bakery sector. Although French legislation provides that collective bargaining agreements may be imposed by law on an entire sector, French law does not oblige the social partners to arrange for supplementary health-care schemes. Hence, the mission to provide these insurance services originated with the private entities concerned and not from the state.[72]

In other words, the ECJ seems to accept that SGEI missions can be derived from general obligations laid down in private collective agreements. In this regard, it should be noted that the social partners must enter into negotiations with the provident organization that will be assigned with the task of administering the health insurance scheme concerned, in order to discuss implementation matters and details. Hence, these negotiations allow this provident organization to influence of what its eventual SGEI mission will consist. There is a stark contrast here with judgments delivered in cases where SGEI did not a play a role. In these cases, such as *Sot. Lélos*, the ECJ firmly rejected the idea that private parties could be engaged in public interest policies. It is hard to reconcile these two lines in the case law.

In sum, we have seen that the application of Article 102 TFEU based on the standard SSNIP methodology has some health-care-specific problems. At the same time, the Commission's new general focus on exclusionary abuse is accompanied by a possible opening for allowing health-care-specific concerns to be taken on board. However, the *Sot. Lélos* case law suggests that this line has not (yet) been adopted by the Court. So far, the main solution for reconciling health-care interests with competition law is found in the application of the SGEI concept. The *AG2R* ruling appears to extend the scope of SGEI beyond the public domain. However, under such a flexible and broad approach, it is very difficult to draw a clear line between undertakings that are entrusted with an SGEI mission and undertakings that are not. We hope that the Court of Justice will soon clarify which conditions an act of entrustment within the meaning of Article 106(2) TFEU must fulfil.[73] This is of special importance given the linkages between national and EU competition laws.

5. The Relationship between the EU Competition Rules and National Rules

NCAs are increasingly called upon to apply competition rules (based on European law) to health-care cases. Hence, it is important to explore how national competition rules relate to European competition rules. This section will address this relationship insofar

[72] Likewise, in Case C-67/96, *Albany*; Joined Cases C-115/97 to C-117/97, *Brentjes*; and Case C-219/97, *Drijvende Bokken*, above n. 15, the ECJ seemed to have accepted that an SGEI mission may be designated by social partners. At issue in these cases were supplementary pension schemes. The provision of such a scheme by a particular pension fund was supposed to constitute an SGEI.

[73] Including the impact of Protocol on Services of General Interest to be annexed to the TEU, to the TFEU, and, where applicable, to the Treaty establishing the European Atomic Energy Community, OJ 2007 C306/148.

as this is relevant for health-care cases. This analysis will mainly concern the *effet utile* (or useful effect) as well as the *CIF* case law and the question of when public involvement in the markets protects the undertakings to which it applies from the competition rules (the 'state action doctrine'). The powers of NCAs with regard to the EU competition rules will also be addressed briefly.

5.1. National and EU competition laws

All EU Member States now have NCAs, which are empowered and obliged to apply Articles 101 and 102 TFEU in cases where trade between the Member States may be affected.[74] In such cases, the Commission must be notified and may itself take control of the case at any point where it believes this is warranted.[75] The NCAs are also members of the so-called network of EU competition authorities (Electronic Communications Network (ECN)) that is coordinated by the EC. These are the results of the modernization of EU antitrust based on Regulation 1/2003,[76] which combines rationalization (a greater emphasis on economic reasoning) and prioritization (more emphasis on hard-core cartels) with systemic reform based on a combination of decentralization and coordination. Meanwhile, all Member States have also adopted national competition laws, which are often carbon copies of Articles 101 and 102 TFEU (a process called spontaneous harmonization). According to Regulation 1/2003, these national rules may not be stricter than the EU rules if an effect on trade is present, unless they apply to unilateral conduct.[77] Hence, the NCAs have to apply both European competition law and national competition rules inspired by their TFEU equivalents.

It is apparent that due to the ECJ's settled case law on the concept of undertaking the door is wide open for applying competition law to health-care cases. This is a significant finding for the NCAs, since they are obliged to interpret the concept of an undertaking in the light of this case law. This is not only true for Article 101 and Article 102 TFEU cases but also in matters involving the national competition rules. After all, these national rules are modelled in line with EU competition law, which implies that the national concept of undertaking is identical to the one developed in the ECJ's jurisprudence. As the majority of the health-care cases are of a national or sub-national nature, the NCAs are required to apply the broad concept of undertaking and, as a result, to develop health-care-specific approaches to competition law.

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[74] Articles 3 and 5 of Council Regulation (EC) No. 1/2003, above n. 6.

[75] *Ibid.*, Arts 11 and 12. Cf. Commission Notice on Cooperation within the Network of Competition Authorities, OJ 2004, C101/43. Amicus curiae interventions by the Commission in national court proceedings are also foreseen: Commission Notice on the Cooperation between the Commission and the Courts of the EU Member States in the application of Arts 81 and 82 EC, OJ 2004, C101/54.

[76] See above n. 6.

[77] *Ibid.*, Art. 3(2).

5.2. Guidance

As was already mentioned, the EC is at the centre of the network of national regulators (ECN) and can trump the procedures of the NCAs by taking over in important cases or in cases where its views diverge significantly from that of the NCA involved. Policy convergence is actively promoted within the ECN. At the same time, undertakings have to perform self-evaluation of their agreements and national courts may be called upon to decide issues of EU competition law. Consequently, the Commission has taken upon itself to provide extensive and regularly updated guidance on such issues as vertical and horizontal restraints and exclusionary abuses.[78] On vertical and horizontal mergers (even though these are not covered by the modernization of antitrust), the Commission has likewise issued detailed explanatory communications.[79] Market definition has also been the subject of a 1997 Commission Notice, albeit by now arguably outdated.[80]

So far, sectoral guidance remains relatively rare and, where it exists, is not always kept up to date,[81] albeit with the significant recent exceptions of distribution agreements in the automobile industry[82] and regarding the insurance industry.[83] Other exceptions are the liberalized network sectors such as electronic communications where during the initial liberalization phase and the transition period more guidance tends to be provided.[84] In any event, apart from the general guidance just mentioned, there is no specific guidance available to NCAs applying the EU competition rules to the health-care sector, even while the broad application of the concept of undertaking opens previously sheltered field up to application of the competition rules. Likewise in the state aid field – where by contrast there is a wide range of sectoral guidance documents[85] – the Commission does not provide specifics for health care.

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[78] Communication from the Commission – Notice – Guidelines on the application of Art. 81(3) of the Treaty, OJ 2004, C101/97; Commission Regulation 330/2010 of 20 Apr. 2010 on the application of Art. 101(3) of the TFEU to categories of vertical agreements and concerted practices, OJ 2010, L102/1; Commission Notice – Guidelines on vertical restraints, OJ 2010, C130/1; Commission Notice – Guidelines on the applicability of Art. 101 of the Treaty to horizontal cooperation agreements, OJ 2011, C11/1; Guidance on enforcement against exclusionary conduct, above n. 62.

[79] Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ 2008, C265/6; Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ 2004, C31/5.

[80] Notice on market definition, above n. 51.

[81] For example, Notice from the Commission on the application of the competition rules to the postal sector and on the assessment of certain State measures relating to postal services, OJ 1998, C39/2.

[82] Commission Regulation (EU) 461/2010 on the application of Art. 101(3) of the TFEU to categories of vertical agreements and concerted practices in the motor vehicle sector, OJ 2010, L129/52.

[83] Commission Regulation (EC) of 24 Mar. 2010 on the application of Art. 101(3) of the Treaty to certain categories of agreements, decisions, and concerted practices in the insurance sector, OJ 2010, L83/1.

[84] Commission Guidelines on market analysis and the assessment of significant market power under the Community regulatory framework for electronic communications networks and services, OJ 2002, C165/6; Notice on the application of the competition rules to access agreements in the telecommunications sector – framework, relevant markets, and principles, OJ 1998, C265/2; Guidelines on the application of EEC competition rules in the telecommunications sector, OJ 1991, C233/2.

[85] With (sometime multiple) separate documents covering agriculture, audiovisual production, broadband broadcasting, the coal industry, electricity, financial services, fisheries, postal services, shipbuilding, steel, synthetic fibres, and transport.

5.3. *Effet utile*

Given the degree of government involvement in health care, the *effet utile* (useful effect) case law is relevant. This is the case law that demonstrates that Member States may infringe their duty of sincere cooperation under Article 4(3) of the Treaty on European Union (TEU) if a Member State by means of its regulation requires or encourages the adoption of agreements, decisions, or concerted practices contrary to Article 101 TFEU or reinforces their effects, or where it divests its own rules of the character of legislation by delegating to private economic operators responsibility for taking decisions affecting the economic sphere.[86] The corollary of this doctrine is that if collusive behaviour is imposed on undertakings by public authorities, the private parties concerned accordingly escape liability under the competition rules (i.e., they may invoke a 'state action defence'), unless they had sufficient margin of freedom to engage in some competition but snuffed this out at their own initiative.[87]

In the Belgian *Doulamis* case in 2008, the Court held that a law prohibiting advertising by dentists did not involve a breach of the *effet utile* of the competition rules because a direct link with private restraints of competition could not be shown.[88] This Belgian case shows – in line with settled case law[89] – that for the useful effect doctrine to be applicable a link should exist between, on the one hand, the restrictive state measures at hand and, on the other hand, particular practices of undertakings. In other Member States, such as the Netherlands, tariff setting based on agreements between the government and bodies of medical practitioners may be vulnerable to the *effet utile* rule if restrictive agreements between the practitioners are promoted by the government in the process. After all, in the light of the useful effect doctrine, it is questionable whether tariff agreements concluded between undertakings are compatible with EU competition law (insofar as they affect the trade between Member States). The limits of what may be permissible are set out in the *Arduino* (2002) and *Cipolla* (2006) cases on the remuneration of Italian lawyers.[90] These cases show that apart from the possibility for public authorities to intervene ex ante (before a particular measure is taken) in the general interest it must be possible for public authorities to take a decision in place of the one proposed by market parties as well (e.g., for judges to adjust rates at a later stage).

5.4. The direct effect of the doctrine of *effet utile*

It is common ground that the EU competition rules have direct effect. This means that they can be invoked by citizens before national courts. In addition, as already mentioned

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[86] Case 267/86, *Pascal Van Eycke v. ASPA* [1988] ECR 4769.

[87] Joined Cases C-359/95 P and C-379/95 P, *Commission and France v. Ladbroke Racing Ltd*. [1997] ECR I-6265.

[88] Case C-446/05, *Doulamis*, above n. 35.

[89] See, e.g., C-245/91, *Criminal Proceedings against Ohra Schadeverzekeringen NV* [1993] I-5851 and Case C-2/91, *Criminal Proceedings against Wolf W. Meng* [1993] I-5751.

[90] Case C-35/99, *Criminal Proceedings against Manuele Arduino* [2002] ECR I-1529; Joined Cases C-94/04 and C-202/04, *Federico Cipolla against Rosaria Portolese and Stefano Macrino and Claudia Capoparte against Roberto Meloni* [2006] ECR I-11421.

above, the NCAs are obliged to enforce Articles 101 and 102 TFEU at the national level in cases that have a European dimension.[91] Application of EU provisions having direct effect by public bodies is in fact inherent in the concept of direct effect.

The 2003 *CIF* case is relevant here as it creates a supplementary responsibility under EU law for NCAs as well as (arguably) other national regulators.[92] In the 1989 *Fratelli Costanzo* case, the Court had already decided that all public bodies, not only domestic courts but also national administrative authorities, such as municipalities, were obliged to apply provisions of European law having direct effect and to set aside those national (legislative) rules that were at odds with these EU provisions.[93] In *CIF*, this was confirmed with regard to the useful effect doctrine discussed above, which means that the undertakings that had so far been protected by the state action doctrine would, henceforth, become liable under EU competition law (albeit not for the period preceding intervention by the NCA). It remains an open question whether this obligation only rests with the national authorities (the NCAs) that have powers to apply Articles 101 and 102 TFEU or whether also other authorities such as health-care regulators have the authority and, as a result, the duty to take action against national measures that are in violation of Article 4(3) TEU in conjunction with Articles 101 and 102 TFEU.

In any event, it is clear that on the basis of the useful effect doctrine NCAs may set aside national health-care interventions that are of a mixed public-private nature. This possibility raises concerns as EU law provides insufficient guidance on whether and to what extent health-care objectives are accommodated in the application of European competition law. An NCA and a national health-care body that is (partly) of a private nature but also legitimized by public law may be involved in a dispute on the compatibility of a particular national measure with European competition law. An example could be collectively negotiated doctor's rates (which is dubious as doctors are, in principle, undertakings) backed up by a related public adjustment of hospital budgets with a view to containing overall costs. Because the case law of the ECJ and the General Court and the decisional practice of the Commission do not clearly address competition law and health-care, it remains uncertain how such a dispute should be settled, that is, EU law does not clearly instruct domestic courts that may have to rule on such disputes. The latter may then make a preliminary reference, raising the entire discussion to the EU level and coincidentally contributing to the de facto emergence of EU health-care

[91] Regulation 1/2003, above n. 6, Art. 3(1): 'Where the competition authorities of the Member States or national courts apply national competition law to agreements, decisions by associations of undertakings or concerted practices within the meaning of Art. 81(1) of the Treaty which may affect trade between Member States within the meaning of that provision, they shall also apply Art. 81 of the Treaty to such agreements, decisions or concerted practices. Where the competition authorities of the Member States or national courts apply national competition law to any abuse prohibited by Art. 82 of the Treaty, they shall also apply Art. 82 of the Treaty.'

[92] Case C-198/01, *Consorzio Industrie Fiammiferi (CIF) v. Autorità Garante della Concorrenza e del Mercato* [2003] ECR I-8055.

[93] Case 103/88, *Fratelli Costanzo Spa v. Comune di Milano en Impresa Ing. Lodigani Spa* [1989] ECR 1839.

law – despite the ban on harmonization in this field.[94] However, the emergence of such an approach depends on the willingness of national courts to address preliminary questions to the ECJ.

6. Conclusion

Above, EU competition law as applied to health-care cases has been analysed. The main question was whether EU institutions accommodate health-care-specific concerns in the way they apply the Treaty provisions on competition to health care. Likewise in question was whether this view was sufficiently clear to allow its application by national authorities.

While addressing these questions, we have found that the case law on the applicability of competition law has paved the way for EU involvement in health-care. This is the first, formal, step: the Commission and the European courts may assess all kinds of health-care practices in the light of competition. On this count, it should be concluded that the European courts and the Commission have construed the concept of undertaking expansively. Cases such as *Pavlov* and *Glöckner* suggest that most providers of health-care are caught by the competition rules because they provide (economic) services (potentially) in competition. Furthermore, *AOK* and *FENIN*, as well as more recently *AG2R*, show that bodies managing health-care schemes fall within the ambit of the European competition law as well, insofar as their schemes are based on a mix of solidarity and competition. In contrast, if these schemes are predominately based on solidarity and are subject to substantial supervision by the state, competition law does not apply. However, the precise lines of demarcation are not easy to draw, and these cases remain difficult to square with some of the other case law. In any event, health-care-specific concerns play an important role in the case law on the concept of undertaking, as solidarity is one of the values taken into account in this case law.

However, what about the second, substantive, step: how do the EU institutions apply Articles 101 and 102 TFEU to concrete health-care cases? Here, the answer to the question of whether there is a health-care-specific application of the competition rules is that no coherent view exists nor does a general exception from application of the competition rules. In this context, it is striking that the ECJ is prepared to pay due consideration to legitimate interests in cases concerning, for example, sports and the professional ethics of lawyers but has not extended this approach to health-care. In cases like *GlaxoSmithKline* and *Sot. Lelos*, no specific awareness of the health-care dimension was evident, while the facts of these cases (e.g., the role of health insurers) and the persistence of the problems of parallel imports of pharmaceuticals and public intervention in pharmaceutical pricing

[94] Cf Art. 168, para. 7 TFEU as well as Art. 6 sub(a) TFEU and Art. 2, para. 5 TFEU, which jointly explicitly make clear that the harmonization of laws in this area is excluded. This notwithstanding a Directive on patients' rights in cross-border health care has recently been adopted by European Parliament and Council, above n. 2.

would have been pertinent. Nevertheless, in individual health-care cases such as *Glöckner* and *AG2R*, exceptions were successfully invoked, notably that for SGEI – albeit with a lack of clarity, for example, on what constitutes entrustment and to what extent SGEI can be defined by private parties.

Altogether this appears to mean that health-care providers, insurers, and managing bodies can benefit from an (albeit so far ill-defined) margin of autonomy with respect to the competition rules, which is broadly conditioned by the answers to questions of whether benefits are fixed in national legislation, whether significant public supervision is involved, and whether restrictions on competition are necessary to enable the functioning of an SGEI, that is, the degree of explicit state involvement codetermines the scope for independent behaviour and, hence, for application of the competition regime (as in a state action doctrine).

Turning to the question regarding the clarity required for action at the national level, the combination of this expansive interpretation of the concept of undertaking in EU law and the decentralization of the application of EU competition policy are likely to require many NCAs to apply EU competition law to health-care cases.[95] National courts will also be confronted more frequently with questions involving EU competition law and undertakings must make self-assessments whether the legal exemption from the cartel prohibition of Article 101(3) TFEU applies. Unfortunately, however, due to the absence of a comprehensive and coherent view on the application of European competition law to health care, there is scant guidance from the EU level when it comes to concrete issues of antitrust control. The problem is that the Commission and the European courts may not get the opportunity to provide more clarity in concrete cases in the near future. With the partial exception of pharmaceuticals, the health-care sector in the EU (both insurance and provision) remains composed of tightly regulated national enclaves with limited cross-border activity. Hence, the Commission and, in its slipstream, the European courts will only come into action occasionally – and have also few incentives to do so, given the political sensitivity of the sector.

The NCAs and national courts, however, are less able to avoid ruling in health-care cases that are at the margin of being EU relevant (requiring appreciable effects on competition and on trade). This means that a fair chance exists that they will come up with their own interpretations and approaches and, as a result, will create a 'Euro-national' competition law for health care that may well be fragmented across the different Member States. This development may fit in with the view of European law as a multilayered

[95] A first account of decisions taken by NCAs in health-care cases can be found in Lear et al., above n. 17. For another recent overview, see A. Taylor et al., 'Healthcare and Competition Law: An Emerging Area – Overview of Cases by European National Competition Authorities', *E-Competitions, Special Healthcare Issue* (January 2011). Moreover, as was already outlined above, the approach taken by the Union Courts in Case C-205/03, *FENIN*, above n. 20 and the preceding Case T-319/99, *FENIN* [2003] ECR II-357 towards buying power in health care and the concept of undertaking significantly differs from the decisional practice of many NCAs that preceded the *FENIN* judgments. Monographs on individual Member States are also emerging, e.g., T. Lubbig & M. Klasse, *Kartellrecht im Pharma- und Gesundheitssektor* (Baden-Baden: Nomos, 2007) for Germany and D. Fornaciari, S. Callens & E. Schokkaert, *Ziekenhuizen, mededingingsrecht en recht op kwaliteitsvolle zorg* (Antwerp: Intersentia 2010) for Belgium.

legal order. Preliminary references may provide a lifeline for the coherence of EU law. However, so far the preliminary reference procedure has not delivered what it is supposed to do: guaranteeing the uniform application of the Treaty provisions to health-care. Moreover, we are convinced that the EU and its Member States should not be satisfied with the current way competition law is shaping health care.

The following problems need to be solved:

(1) First, the application of the Euro-national competition rules for health care is vulnerable to unexpected changes in law. As the *AOK* case law had made clear, as soon as the ECJ comes up with a decision that deviates from long-standing national practices, NCAs must immediately change their policy. This is damaging to the reputation of an NCA and bad for legal certainty. The law must be more predictable.

(2) Second, NCAs risk developing diverging sets of Euro-national competition rules for health care. This seems inevitable, as these national authorities must work out EU competition law, which largely consists of open norms and concepts, in widely different settings. As a result, what is permissible in one Member State may be forbidden in another. Such a development would obviously interfere with the establishment and functioning of the internal market. Hence, the recent progress made in free movement law could be jeopardized by divergence in EU competition law.

How can these problems be solved? We are not pleading for the European legislature to enact hard law harmonization measures, even if such a development were conceivable. However, we do believe that the EU level should take charge of shaping the basic tenets of the Euro-national competition rules for health care and the development of the resulting multilayer model in competition and health care. Hence, the Commission should develop a coherent approach towards competition law and health care, in close cooperation with the NCAs. The framework of the ECN seems suitable for such discussions, which could culminate in soft law documents such as guidelines or communications. Key points to be addressed in these documents are related to the role of the 'legitimate objectives' case law in *Wouters* and *Meca-Medina* in health care. Furthermore, they should examine the role that SGEI could play, as the ECJ's case law has shown both that this concept is capable of reconciling the EU competition rules with health-care objectives (allowing for mixed systems with a controlled degree of reliance on the market and on private operators) and that the exact contours of this concept remain hard to grasp. This concerns, for instance, the degree to which SGEI can be defined and/or entrusted by private parties and, hence, when the exemption can be invoked. The practical implications of this are considerable. Here too, therefore, clarification on how to apply key competition concepts in the health-care context is required.

Hence, EU competition law will have to show that it is equal to the challenge of offering the health-care sector a comprehensive and coherent competition law

framework. This is all the more important as Member States are trying out varying degrees of market-based reform in this sector. It is also important because for similar reasons other pillars of the welfare state such as education, social services, and pensions are likely to be more affected by the EU competition rules in the near future. Therefore, the lessons learned from the application of competition law in health care are essential in order to meet the challenges imposed by market-based changes in the functioning of the European welfare states at large.

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Please direct submissions to:
James Mathis, Managing Editor
Legal Issues of Economic Integration
Department of International Law
University of Amsterdam
PO Box 1030
1000 BA Amsterdam
The Netherlands

e-mail: J.H.Mathis@uva.nl